

- (b) Reliance on a "per se" rule of obviousness purportedly established by In re Venner is improper, particularly because the automatic audiometric testing system provided by the claimed invention does not merely achieve the same result as prior systems that required a human test administrator to address errors, provide corrective instructions, and resume testing.
  - (c) Delisle et al. does not provide any teaching or suggestion to modify the '310 publication and Slavin in a way that would eliminate the need for a human test administrator to address errors, provide corrective instructions, and resume testing.
- (2) Objective evidence of secondary considerations is presented to rebut the prima facie case of obviousness.
- (a) Declarations of Theresa Y. Schulz, Jack Foreman and Juan F. Hernandez provide evidence of the commercial success of products embodying the invention.
  - (b) The Declarations of Theresa Y. Schulz and Juan F. Hernandez provide evidence that experts in the field of hearing conservation thought that the claimed features of the invention had a tremendous impact in the industry, beyond what other systems and literature at the time of the invention could provide.

Claim 21 was rejected under 35 U.S.C. 103(a) as being unpatentable over the '310 publication in view of Slavin and Delisle as applied to claim 16, and further in view of the RION AA-75 Audiometer Operation Manual (the RION manual). This rejection is

traversed by the aforementioned traversal of the rejection of independent claim 16, since claim 21 depends from claim 16 and for at least that reason is allowable therewith.

### DETAILED RESPONSE TO REJECTIONS

#### Claims 6-20 (35 U.S.C. 103)

Claims 6-20 were rejected under 35 U.S.C. 103(a) as being unpatentable over JP 07-308310 (the '310 publication) in view of Slavin (USP 4,489,610) and Delisle (USP 3,809,811).

#### Claim 12 - Recited Elements

Claim 12 recites a computer adapted to perform an audiometric test of a subject that includes

- a test tone generator operable to deliver audible test tones to earphones worn by the subject
- an input/output interface, and
- software programmed to control the test tone generator to deliver the audible test tones to the earphones worn by the subject, monitor responses by the subject received over the input/output interface, detect errors in the subject's responses, selectively deliver audible corrective instructions to the earphones in response to the detected errors, and automatically resume delivery of the audible test tones after the audible corrective instructions are delivered without human intervention.

Claim 12 – Examiner's Rejection

Regarding claim 12, the Examiner contended that

the '310 publication discloses a computerized audiometer 1 comprising a test tone generator 4 operable to deliver audible test tones to speakers 9, 10; an input/output interface SI3, S2I; and a central processing unit 3 comprising software programmed to control the test tone generator to deliver test tones to speakers 9, 10, monitor a subject's responses to the tones, detecting when an error has occurred in the test subject's responses, and delivering a message to a display 26 to notify the examiner and/or patient that the response from the patient is a mistake. See paragraph 8. The '310 publication discloses a restart button on control panel 2 in order to resume delivery of the test tones once the examiner has provided audible corrective instructions to the patient. See paragraphs 42 and 43. ... Accordingly, the primary difference between the claimed invention and the prior art consists in providing software to deliver audible corrective instructions to the earphones in response to the detected errors, and automatically resume delivery of the audible test tones after the audible corrective instructions are delivered.

In order to rectify the noted difference between the claimed invention and the prior art, the Examiner pointed to paragraph 84 of the '310 publication, which states "it may be made to have display 26 on patient side and directly instruct patient to release the response button 24A with the display 26," and to paragraph 85 of the '310 publication, which states "the means of notification is no restricted within this" (notification of errors via alarm 25 and display 26), and "a lamp may be used which lights when patient is keeping to press response button 24A or when patient is operating response button to press down by reacting to masking noise, or this may be notified with voice." The Examiner also pointed to Slavin, contending that this patent "discloses an audible instruction generator 16 under the control of a central processing unit 12 for providing audible instructions to a user for the conduct of an audiometric test (see column 2, lines 35-43)." In view of these teachings, the Examiner contended that "It would have been

obvious in view of Slavin to provide an audible instruction generator under the control of the central processing unit 3 of the '310 publication for the purpose of providing audible instruction to the test subject in order to correct the error, i.e., to instruct the subject to release the response button."

The Examiner further contended that "It would have been obvious to automatically resume delivery of the audible test tones after the audible corrective instructions are delivered." The rationale for this modification was provided as a matter of law, citing In re Venner for the proposition that "The mere replacement of a manual operation with an automatic operation that accomplishes the same result is generally considered to be a design consideration within the skill of the art." The Examiner also contended that this object was recognized in the art at column 1, lines 57-64 of Delisle et al.

#### Claim 12 - Response

##### A. RESPONSE TO PRIMA FACIE OBVIOUSNESS

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. See M.P.E.P. 2143.

In this case, there are two modifications/combinations proposed by the Examiner. First, the Examiner admitted that the primary reference (the '310 publication) does not disclose providing audible corrective instructions to a test subject in response to a detected error. The Examiner contended that it would have been obvious to modify the '310 publication to provide this capability in view of the teachings of Slavin, which is

cited as disclosing an audible instruction generator under the control of a CPU for providing audible instructions to a user for taking an audiometric test.

Slavin discloses an audible instruction generator that "may take the form of a continuously cyclable tape or record player or a voice synthesizer operating under the control of the central programming unit and adapted to provide a series of audible instructions to the user for the conduct of the test in proper sequence and with the proper pauses..." Column 2, lines 36-41. While Slavin characterizes this system as an "automatic" audiometer, it is clear that this system is only capable of performing a test automatically if the test subject completes the test flawlessly, without any errors, since the pauses and sequences of instructions and tones are preset according to a preordained schedule.

The Examiner proposes modifying the '310 publication to incorporate the audible instruction generator of Slavin. The motivation for this modification is explained as being "for the purpose of providing audible instruction to the test subject in order to correct the error..." However, this motivation is not found anywhere in the record, but instead comes from the instant patent application. The '310 publication discloses notifying a test administrator of an error, by indicating that "patient response button has been pressed," or "patient is responding to masking noise, push start button when explanation is complete," for example. The '310 publication indicates that the display providing this notification may be on the patient side in order to directly instruct the patient to release the response button. Slavin discloses a system that does not respond to errors in any way, but instead plays preset instructions with preset pauses and sequences that preclude responding to any errors made by the test subject.

In order to modify the '310 publication to employ voice instructions in response to errors, there must be a suggestion or motivation in the record that would lead a person of ordinary skill in the art to make this modification. See M.P.E.P. 2143.01, citing

In re Linter, 458 F.2d 1013, 1016 (C.C.P.A. 1972). In support of a proposed motivation, "particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed." In re Rouffet, 149 F.3d 1350, 1359 (Fed. Cir. 1998). Here, the disclosure in Slavin of an audible instruction generator that generates preset, timed instructions would not have motivated one of ordinary skill in the art to employ dynamically selected voice instructions in response to errors, as the Examiner has contended. Slavin illustrates that the generation of voice instructions was technologically known, but in order to modify the '310 publication to provide specific voice instructions to a test subject in response to errors, there must be some suggestion or motivation on the record to do so, and no such suggestion or motivation has been shown. "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." M.P.E.P. 2143.01, citing In re Mills, 916 F.2d 680 (Fed. Cir. 1990). In this case, Slavin does not suggest the desirability of the combination, since Slavin does not deal with error correction or any type of dynamic instruction.

In addition, the Declaration of Theresa Y. Schulz submitted herewith provides further evidence that the teachings of Slavin would not have motivated a person skilled in the art of hearing conservation to modify a system such as is disclosed in the '310 publication to automatically provide selective audible corrective instructions in response to a detected error. See Declaration of Theresa Y. Schulz at paragraphs 27-31.

Therefore, because the requisite suggestion or motivation to modify the teachings of the references in the manner claimed is lacking for the reasons discussed above, a prima facie case of obviousness has not been properly established, and the rejection of claim 12 under 35 U.S.C. 103(a) should accordingly be withdrawn.

Second, the Examiner admitted that the combination (as proposed) of the '310 publication and Slavin does not disclose automatically resuming delivery of audible test tones after audible corrective instructions are delivered (in response to a detected error) without human intervention, as recited in claim 12. The Examiner contended that "It would have been obvious to automatically resume delivery of the audible test tones after the audible corrective instructions are delivered." The motivation for this modification was taken from In re Venner which is cited as stating "the mere replacement of a manual operation with an automatic operation that accomplishes the same result is generally considered to be a design consideration within the skill of the art," and also from a contention that Delisle et al. recognized the object of providing an automatic audiometer that no longer requires the invention of an operator.

The Examiner's reliance on a "per se" rule of obviousness purportedly provided by In re Venner is improper. Reliance of per se rules of obviousness has been noted by the Federal Circuit as being "legally incorrect and must cease." In re Ochai, 71 F.3d 1565, 1572 (Fed. Cir. 1995). Instead, the facts of each case are to be considered on their own merits and examined in light of all relevant factors. See Id. The quoted statement of Venner refers to replacement of a manual operation with an automatic operation *that accomplishes the same result*. Merely replacing the restart button of a system based on a combination of the '310 publication and Slavin with an automatic switch would not accomplish the same result as the claimed invention. The system of the '310 publication is predicated on the role of a human test administrator to instruct the test subject how to respond to an error and avoid future errors. Even the messages displayed do nothing more than notify the test administrator of the existence of a particular error, with the expectation of intervention by the administrator explicitly stated in the message itself, which states "push start button **when explanation is complete.**" Thus, in the context of the

'310 publication (and all other systems of this type), human intervention in response to errors is critical to proper error recovery. This concept is further supported by the attached Declaration of Theresa Y. Schulz, an expert in the field of hearing conservation, explaining the extensive training of human test administrators that is required to ensure that instructions in response to errors are effective and understood, and to ensure that successive tests proceed in a consistent manner. See Declaration of Theresa Y. Schulz, paragraph 23. Thus, the result that would be obtained by simply replacing the restart button of the '310 publication with an automatic switch would not accomplish consistent and effective testing, because of that system's reliance on the expertise of the human test administrator to recover from errors. This is different from the result obtained in the system disclosed and claimed in the present application, which provides consistent results by automatically delivering audible corrective instructions that instruct the test subject how to change his/her response behavior and avoid further errors, and which automatically resumes the delivery of test tones after corrective instructions are delivered in order to speed testing and reduce the burden on human test administrators to intervene in response to an error.

The Examiner's further reliance on the teachings of Delisle et al. is also misplaced. Delisle et al. states at column 1, lines 57-64, that it is an object of the invention "to provide a computing automatic audiometer which no longer requires the presence of a trained audiologist and which is characterised by having its entire operation managed by a computer program, the successive execution of the test being carried out without any intervention by the operator." The Examiner concluded from this teaching that the object of eliminating the test administrator in recovering from errors was recognized in the art. However, further review of Delisle et al. shows that this is not the case. Delisle et al. teaches an automated system of controlling the sequence of tone frequencies presented to



the test subject, which at that time had required the expertise of a trained audiologist. Once testing begins, the sequence of tone frequencies is controlled by a computer based on responses by the test subject, but there is no disclosure, teaching or suggestion of detecting errors, delivering corrective instructions in response to detected errors, or resuming testing after an error has occurred. Thus, Delisle et al. operates on the assumption that no errors occur during testing. This teaching cannot be relied upon to provide a rationale for eliminating a human test administrator in the handling of errors.

In addition, the Declaration of Theresa Y. Schulz submitted herewith provides further evidence that the teachings of Delisle et al. would not have motivated a person skilled in the art of hearing conservation to modify a system such as is disclosed in the '310 publication and the Slavin patent to automatically resume the delivery of test tones without human intervention after audible corrective instructions have been delivered. See Declaration of Theresa Y. Schulz at paragraphs 27-31.

Therefore, it is not proper for the Examiner to modify the combination of the '310 publication and Slavin, based on mere legal precedent or on the teachings of Delisle et al., to automatically resume delivery of audible test tones after audible corrective instructions are delivered without human intervention. Because the requisite suggestion or motivation to modify the teachings of the references in the manner claimed is lacking for the reasons discussed above, a prima facie case of obviousness has not been properly established, and the rejection of claim 12 under 35 U.S.C. 103(a) should accordingly be withdrawn.

#### B. REBUTTAL OF PRIMA FACIE OBVIOUSNESS

Even if the prima facie case of obviousness has been established, the Applicant provides substantial objective evidence with this Response to rebut the prima facie case of obviousness, which evidence must be considered when present. See M.P.E.P.

2141 and 716.01(a), citing Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1538 (Fed. Cir. 1983).

The Declarations of Theresa Y. Schulz, Jack Foreman and Juan F. Hernandez provide evidence of the commercial success of products embodying the invention. The Declaration of Theresa Y. Schulz describes the process of granting a Department of Defense contract in 1998 for approximately 2000 audiometers to the Maico MA-1000 audiometer, which included the capability to switch from the delivery of test tones to the delivery of audible corrective instructions to a listener in response to a detected error in the listener's responses to the test tones, and to automatically switch back to the delivery of test tones to resume testing after delivering corrective instructions without human intervention (as recited in claim 12). See Declaration of Theresa Y. Schulz at paragraph 26. This Declaration also explains that the commercial success of the Maico MA-1000 audiometer in being awarded this contract was due to this capability, as a system lacking this capability (such as the cited prior art) would have received an unfavorable evaluation because of the lack of this capability. See paragraphs 25 and 26. This evidence therefore provides the nexus between the claimed invention and the evidence of commercial success. The commercial success was achieved in a transaction that occurred at arms length, and was not related to advertising or other external factors, indicating that the success was truly attributable to the claimed invention.

The Declaration of Jack Foreman explains that the sale of approximately 2500 audiometers in the contract awarded by the Department of Defense in 1998 was significant in the overall market for audiometers. This Declaration also describes the continued commercial success of audiometers that embody the invention in comparison with audiometers that do not.

The Declaration of Juan F. Hernandez provides further evidence that products embodying the invention have greater commercial success than products that do not embody the invention. See Declaration of Juan F. Hernandez at paragraphs 11-13.

The Declarations submitted with this Response establish that products embodying the invention have had substantial commercial success, that the success was attributable to the specific claimed features of the invention, and that this success was greater than the success achieved by products that did not embody the invention. This evidence indicates that the features recited in claim 12 (selectively delivering audible corrective instructions to the earphones in response to the detected errors, and automatically resuming delivery of the audible test tones after the audible corrective instructions are delivered without human intervention) are not obvious.

The Declarations submitted with this Response also provide additional objective evidence of nonobviousness. In particular, the Declarations of Theresa Y. Schulz and Juan F. Hernandez show that experts in the field of hearing conservation thought that the invention had a tremendous impact in the industry, specifically because of the ability of products embodying the invention to detect errors, provide corrective instructions, and automatically resume testing without intervention by a human test administrator. This capability allowed multiple subjects to be tested simultaneously in a short period of time, ensured that successive tests would be performed effectively and consistently, and reduced the administrative burden on facilities and personnel that provide hearing testing services by re-instructing test subjects and resuming testing automatically after an error condition is detected, rather than requiring a specially trained and possibly multilingual test administrator to perform these functions. In addition, the Declaration of Theresa Y. Schulz provides evidence that the Examiner's interpretation of the '310 publication is not an operable interpretation. The '310 publication suggests in paragraph 84 that the display

26 could be located on the patient side of the system and directly instruct the patient to release the response button 24A. The Examiner has interpreted this disclosure, in combination with Slavin, and in further combination with legal precedent (In re Venner) and Delisle et al., as meaning that this instruction could be used instead of the human test administrator and that testing could be restarted after this type of instruction automatically without involvement by the test administrator. Paragraphs 23 and 24 of the Declaration of Theresa Y. Schulz indicate that the notification messages provided by the system described in the '310 publication are not sufficient to re-instruct a test subject after an error has occurred, and that a human test administrator is required in systems of this type to ensure that tests are performed effectively and consistently. Thus, this evidence shows that any interpretation of the '310 publication as suggesting elimination of a human test administrator is not operable.

In view of the objective evidence submitted with this Response, there is sufficient evidence to overcome the evidence on the record of obviousness. Reconsideration and allowance of claim 12 is accordingly respectfully requested.

Claims 13 and 14

Claims 13 and 14 depend from independent claim 12, and are allowable therewith.

Claims 6-11 and 15

Independent claim 6 recites a multimedia audiometer that includes

- audio circuitry capable of generating test tones for delivery to earphones worn by a test subject;
- a computer selectively operable to produce instructions represented by sound waves for delivery to the earphones;
- microprocessor circuitry operatively coupled to the computer;

- an interface operatively coupled to the computer and the microprocessor circuitry for signaling whether the test subject perceives the audible test tones;
- a switch having a first state in which audible test tones generated by the audio circuitry are provided to the earphones, and a second state in which the instructions represented by sound waves produced by the computer are provided to the earphones; and
- software stored in at least one of the computer and the memory of the microprocessor circuitry for operating the system, detecting errors in the test subject's responses to test tones, selectively producing the instructions in response to the detected errors, and controlling the switch to switch to the second state when errors are detected in the test subject's responses and to automatically switch back to the first state following delivery of the instructions to the earphones so that testing is resumed without human intervention.

Claim 6 was rejected on the same bases discussed above with respect to claim 12. For the same reasons discussed above with respect to claim 12, and in view of the objective evidence submitted with this Response and discussed above, the rejection of claim 6 under 35 U.S.C. 103(a) should be withdrawn.

Claims 7-11 and 15 depend from independent claim 6, and for at least that reason are allowable therewith.

#### Claims 16-20

Independent claim 16 recites a method of performing an audiometric test of a subject that includes

- controlling an audiometer to generate audible test tones in a headset worn by the subject;
- monitoring responses to the audible test tones by the subject;
- detecting errors in the subject's responses to the audible test tones;
- storing the detected errors in a computer memory;
- automatically producing selected audible corrective instructions in response to the detected errors and switching an input to the headset to the audible corrective instructions; and
- automatically switching the input to the headset back to the audible test tones after the audible corrective instructions are produced.

Claim 16 was rejected on the same bases discussed above with respect to claim 12. For the same reasons discussed above with respect to claim 12, and in view of the objective evidence submitted with this Response and discussed above, the rejection of claim 16 under 35 U.S.C. 103(a) should be withdrawn.

Claims 17-20 depend from independent claim 16, and for at least that reason are allowable therewith.

Claim 21 (35 U.S.C. 103)

Claim 21 was rejected under 35 U.S.C. 103(a) as being unpatentable over the '310 publication in view of Slavin and Delisle as applied to claim 16, and further in view of the RION AA-75 Audiometer Operation Manual (the RION manual).

Claim 21 depends from independent claim 16, and for at least that reason is allowable therewith.

Claims 16-21 (Double Patenting)

Claims 16-21 were provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 6-9, 11 and 19 of copending Application No. 11/043,408. Application No. 11/043,408 has been abandoned, and this provisional rejection should accordingly be withdrawn.


CONCLUSION

In view of the foregoing, all of the pending claims (6-21) are in condition for allowance. A notice to that effect is respectfully requested.

Respectfully submitted,

KINNEY & LANGE, P.A.

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By: 

Alan M. Koenck, Reg. No. 43,724  
THE KINNEY & LANGE BUILDING  
312 South Third Street  
Minneapolis, MN 55415-1002  
Telephone: (612) 339-1863  
Fax: (612) 339-6580

AMK